

EPA's SBAR Panel Outreach Meeting with Small Entity Representatives on Proposed Rulemaking for Methylene Chloride under TSCA Section 6(a)

Key Takeaways from Pre-Panel Outreach Meeting

On November 4, 2020, EPA conducted a Pre-Panel outreach meeting with potential small entity representatives (SERs). Representatives from SBA and OMB also participated. A total of 20 potential SERs participated in the meeting. EPA presented an overview of the SBAR Panel process and Section 6 of TSCA, an explanation of the forthcoming rulemaking, potential regulatory approaches, and cost estimates. EPA also provided opportunities for questions and feedback. Three SERs provided materials in advance of the meeting to share during the discussion; these included responses to EPA's questions to SERs and process diagrams. EPA asked the potential SERs to provide written comments by November 18, 2020.

At the Pre-Panel outreach meeting, SERs provided information on the number and type of entities that would be affected (including descriptions of their processing or use of methylene chloride, their customer base, and how their products are used); potential compliance requirements (including current exposure monitoring and reduction, anticipated changes due to future requirements, and considerations for substitute chemicals); related Federal rules; and potential regulatory flexibility alternatives (including descriptions of challenges for small businesses and questions for EPA regarding the regulatory approach). SERs emphasized that more specificity on what exposure level EPA might require was necessary before they could fully describe potential impacts to their businesses.

Summary of Comments from Potential Small Entity Representatives

Number and Types of Entities Affected

SERs discussed their processing or use of methylene chloride, as well as their customer base and how their products are used. Specifically, SERs described:

- Polycarbonate manufacturing:
 - One SER uses methylene chloride to make polycarbonates used in medical, pharmaceutical, and military applications. The SER described the process by which methylene chloride is used as a reaction solvent, and then distilled and recycled. The SER adds the reactants from tank trailers with hard pipes and flange fittings, and the product is also packed out under vacuum in a scrubber system to reduce employee exposures. This SER described how the customers of its polycarbonate products are small businesses making specialty devices.
- Chemical manufacturing:
 - One SER described its facility for manufacturing chemicals and pharmaceuticals; the facility uses methylene chloride as a functional fluid in a closed-loop engineered heat-transfer system, which runs throughout the facility.
 - One SER uses methylene chloride in pesticide manufacturing as a solvent, where it is recovered and reused.

EPA's SBAR Panel Outreach Meeting with Small Entity Representatives on Proposed Rulemaking for Methylene Chloride under TSCA Section 6(a)

- One SER uses methylene chloride as a processing agent, and all its products are exclusively for research and development or a pharmaceutical use. This SER has experience working with methylene chloride and described the strength of its engineering controls.
- Paint and coating removal:
 - Processors and distributors in this group make paint removers mostly used by the furniture refinishing industry. One SER indicated that one of its customers using methylene chloride for antique restoration indicated that this product is preferred because it can penetrate the paint layers without destroying the wood substrate.
 - Another SER has been in business for 45 years manufacturing methylene chloride products, mostly paint removers used by the furniture refinishing industry. This SER described how it sells its methylene chloride paint and coating remover to thousands of furniture refinishers and other industrial applications. The SERs manufacturing paint and coating removers discussed how coating technology on furniture has dramatically improved, and how, in their view, methylene chloride is by far the most effective product for removing coatings from wood.
- Degreasing, adhesives, or other products:
 - One SER sells an automotive brake cleaner containing methylene chloride, both in aerosol and in liquid form in 1- to 55-gallon containers. Proper automotive usage of it is in a typical garage, but it is possible that consumers are purchasing the products. The SER described its sales as directly to distributors and wholesalers, rather than to direct end users. The SER is aware some customers may be using its products for specialty uses, such as non-automotive machinery in oil fields.
 - Another SER described how some of their customers (mechanics) may purchase and use immersion cleaner products that contain methylene chloride primarily for automotive (e.g., 4-barrel carburetor) and non-automotive (e.g., lawn mower) carburetor cleaning.
 - One SER manufactures adhesives, mostly of solvent-born materials; the SER estimated that 40% of its products contain methylene chloride. These products contain about 65-75% methylene chloride, which are packaged into a pressurized canister.

Potential Reporting, Recordkeeping, and Compliance Requirements

SERs described their current exposure monitoring and reduction practices, anticipated changes due to potential requirements from EPA, and considerations for substitute chemicals or processes. Specifically, SERs described, for themselves or their customers:

- Engineering and administrative controls:
 - Closed loop systems in place, with other controls:

EPA's SBAR Panel Outreach Meeting with Small Entity Representatives on Proposed Rulemaking for Methylene Chloride under TSCA Section 6(a)

- One SER, a formulator of paint removers, blends solvents and pumps them through closed lines using ventilation in their mixers and filling apparatus. In addition, the SER described a combination of engineering and administrative controls with personal protective equipment (PPE) in place, such as employees using APF 50 respirators, and isolating the manufacturing building from the rest of the facility.
- Another SER with a closed system described employee exposure to methylene chloride during the introduction process and maintenance activities, such as spot ventilation or a line break. The SER described how these activities are carried out with engineering controls and the use of PPE. The company conducts industrial hygiene monitoring of these activities and states that it sees no or extremely low concentrations of methylene chloride.
- One SER with a closed system emphasized that any exposures would occur when a line breaks or in a maintenance situation. In this situation, the employees use PPE and have standard operating procedures (SOP) on how to clear the system safely. Similarly, another SER described how, during equipment failure or maintenance activity, the group of employees who could potentially be exposed wear chemical resistant suits and have supplied air respiratory protection.
- One SER described how it utilizes administrative controls like SOPs and training.
- Exhaust and ventilation:
 - One SER described how its coating removal customers (furniture refinishers) are likely only exposed to methylene chloride for a few hours a week. In the SER's estimation, very few of the SER's customers (the furniture refinishers) are exposed to methylene chloride over 20 hours a week, and the SER's customers that are exposed to methylene chloride over 20 hours a week would use a ventilation apparatus that would draw the air from behind the worker and towards the back end of the facility and ventilate it out. Small furniture refinishing businesses or furniture refinishers working on small projects might work outside to reduce exposure.
 - Another SER has storage and blending tanks outside and underground. The SER described how it transfers the chlorinated solvents from one tank to another, then turn the tank over until it is mixed. The entire back wall of the facility has large 4-foot exhaust fans to filter air through the facility.
 - One SER described how its customers that are larger businesses tend to recognize that more exposure controls are needed and may have an exhaust fan nearby. In general, the SER expects that these customers use a relatively small amount of methylene chloride per day (noting that the customers might spray 5-10 pounds of material in an 8-hour shift).
 - Another SER stated that, generally, smaller businesses like themselves are harder to train on how to use products containing methylene chloride and may have

EPA's SBAR Panel Outreach Meeting with Small Entity Representatives on Proposed Rulemaking for Methylene Chloride under TSCA Section 6(a)

difficulty implementing engineering controls. However, the SER stated that smaller businesses typically use a smaller amount of product, do not go over the exposure limit per day, and open doors and windows to help with air flow.

- One SER described potential limits of engineering controls in certain contexts, stating that reducing exposure levels is impractical if not impossible when dealing with furniture refinishing. The SER described how in a booth environment it may not be possible to increase ventilation to what may be necessary (the SER estimated ventilating at airflow rates of 100 ft per minute), and how closed systems are not practical for furniture repair because of the varying size of furniture.
- Administrative controls:
 - One SER (a formulator of paint remover products containing methylene chloride) described how customers (e.g., furniture refinishers) who use the SER's products for architectural or furniture paint and coating removal carry out most of the work at the furniture refinisher's facility. When on-site work occurs, the furniture refinishers will take all doors and cabinets back to the furniture refinisher's facility. There is potential for occupational non-user (ONU) exposure at that time, which can be mitigated by requiring evacuation of the house and PPE.
 - This SER saw some problems with methylene chloride use in bathtub refinishing and has informed their commercial customer base not to carry out that type of job.
- Personal protective equipment
 - Several SERs were supportive of the requirement to wear PPE or other respiratory controls and implement worker protocol, training, or certification programs.
 - One SER described how in pesticide manufacturing, the greatest possibility for exposure occurs during drum handling, unloading, and emptying procedures. They use PPE in these situations.
 - One SER described how, due to the 1998 Occupational Safety and Health Administration (OSHA) regulations, they developed ventilation systems and safe work practices. They have a manufacturing facility where they use localized ventilation and assigned protection factor (APF) 50 half mask respirators, which they state are effective at keeping exposures below OSHA action levels.
- Monitoring and recordkeeping
 - Several SERs indicated they use badge monitoring to identify the levels of their employees' exposure to methylene chloride.
 - One SER described three ways to monitor employee exposure: First: a badge monitor, which is small, light, and portable, and is attached near the breathing zone and is about a half-inch thick. This method is reliable, passive, and works well, but must be sent to a certified lab for evaluation. Second: the more traditional industrial hygiene tube capture pump, which this SER contends is clunky and must be strapped on to the employee. Third: a portable or stationary

EPA's SBAR Panel Outreach Meeting with Small Entity Representatives on Proposed Rulemaking for Methylene Chloride under TSCA Section 6(a)

monitoring device, which uses similar technology to a volatile organic compound (VOC) detection device.

- One SER described how employees are kept out of the area where people are working with methylene chloride. They do a badge test once a year to make sure employees are not exposed to methylene chloride above OSHA levels. The SER reported that the last time they conducted monitoring, the exposure level was less than half of the OSHA PEL of 25 ppm (i.e., the level was below 12.5 ppm). Anytime a worker encounters methylene chloride they use appropriate PPE, like gloves.
- Exposure limits
 - One SER uses a 12.5 ppm PEL and has voluntarily adopted an action level of 6 ppm; most of the SER's activities do not measure exposures at that level. They did not provide the level they achieved but asserted that closed systems achieve good results.
 - Another SER similarly did not provide their exposure levels but stated that their monitoring data show methylene chloride exposure much less than the OSHA PEL and action level.
- Other compliance strategies:
 - Labeling and container size: To facilitate communication between the formulator and customer, one SER has put a Safety Data Sheet (SDS) on every container for the purposes of downstream notification. The smallest methylene chloride product they sell is a 5-gallon pail which has the SDS enclosed so that if a customer takes a product offsite, they have information available at their fingertips.
 - Assumption of low or no exposure: One SER described their assumption that methylene chloride exposure with immersion cleaners is very fleeting when the part is pulled out and a thin residual layer of methylene chloride is present.
- Substitutes: Several SERs described the benefits to their business of using methylene chloride and their concerns with potential substitutes.
 - Specifically, one SER described how methylene chloride is a very good universal solvent for all industrial and commercial products because it is effective, non-flammable, quick dry, and low odor. A separate SER describes how methylene chloride evaporates quickly, creating efficient and fast production speed.
 - Another SER described how its customer base is interested in keeping some methods of using methylene chloride because it is non-flammable, and other alternatives are not as viable or as effective. This SER added that coating technology on furniture has dramatically improved, and methylene chloride is by far the most effective product for removing coatings from wood. The SER also described how viable alternatives, such as caustics, have flammability, waste, or toxicity issues.

EPA's SBAR Panel Outreach Meeting with Small Entity Representatives on Proposed Rulemaking for Methylene Chloride under TSCA Section 6(a)

- An additional SER stated that flammable alternatives are about 90% as effective but could increase insurance costs and non-flammable alternatives are similarly effective but triple the cost of methylene chloride. The SER also expressed concerns about using flammable solvents near wood.
- Several additional SERs indicated that methylene chloride is the best product available because it is very tiny (one carbon molecule), which is why it is a good penetrant for coatings and such a good degreaser. The SERs indicated that methylene chloride is non-flammable, VOC exempt, and cheap.
- Specific substitutes that SERs identified include:
 - Ethylene dichloride: One SER stated this is a possible alternative, but may be just as hazardous, if not more so. When making polycarbonates, they use a phosgene chemistry, and all the filtrates and reaction products are distilled and brought back to the beginning of the process in a closed loop system. They add the reactants in from tank trailers with hard pipes and flange fittings, and the product is also packed out under vacuum in a scrubber system so there is no exposure to their employees. The SER stated that methylene chloride is an ideal solvent for this use because it has a high vapor pressure, low boiling point, and it is easy to drive it out of the product with a vacuum distillation or filtration.
 - As a low-cost alternative, some SERs described how many users may adopt perchloroethylene (for degreasing).
 - Another SER described how alternatives such as benzyl alcohol, Methylated Seed Oil (MSO), n-Methylpyrrolidone (NMP), and perchloroethylene do not work as well in a paint stripping formulation.
 - One SER uses methylene chloride as a formulation component for dry disulfide lubricants in the oil field industry for pipes in the drilling process. The SER described how methylene chloride works well in this application because it dries quickly, is non-flammable, and leaves behind a lubricant, which serves as a long-lasting barrier to moisture. Alternatives, such as acetone, are usually highly flammable and cause rust.
 - There may be one or more Military Specification (MIL-SPEC) standards for the Department of Defense (DOD) where methylene chloride is the best-case solvent because of its quick drying time, lack of acidity, lack of rust issues, and longevity of the dry coating.
- SERs estimated the business impacts of switching to substitutes:
 - One SER found a flammable solvent as a substitution material. It would require changes to many instruments, motors, electrical classification, wall separation, HVAC revisions, and sprinkler changes. They estimate the cost around \$300,000 - \$400,000.

EPA's SBAR Panel Outreach Meeting with Small Entity Representatives on Proposed Rulemaking for Methylene Chloride under TSCA Section 6(a)

- One SER described how flammable alternatives are about 90% as effective and nonflammable alternatives are similarly effective, but triple the cost of methylene chloride. They do not have a good alternative yet for 3 or 4 of their products. It would take about 100 or more hours of lab time to develop alternatives, at a cost of about \$50,000-100,000.
- A separate SER stated that if there was a significant new regulation or elimination of methylene chloride, their own business would be heavily affected because it takes time to find and sell new products. It is hard to quantify what their costs would be to switch to new materials.
- One SER described how their customer base prefers products with methylene chloride in it, and how, for paint strippers, it is difficult to reformulate the product without methylene chloride.
- One SER has some acceptable alternatives for adhesive products containing methylene chloride, and the key additional cost burden would be to get out and sell those materials to customers who are using methylene chloride currently. They have about 2,000-3,000 smaller end users of the material; the SER is concerned about losing their business in the process of switching to something new.

Related Federal Rules

When discussing related Federal rules, the SERs focused on current OSHA requirements:

- Many SERs indicate they follow OSHA standards and believe the standard to be adequate.
- One SER described how they use safe work practices, localized ventilation, and PPE such as APR 50 half mask respirators. They include Safety Data Sheet (SDS) on every methylene chloride product container and do downstream notification.
- One SER emphasized that they can comply with OSHA and believe the standards are adequate to operate safely. Their process does not require a closed system or a pressurized heating system. They monitor and report to the Toxics Release Inventory (TRI) and the state air pollution control district.
- One SER felt the OSHA exposure level is very safe.
- Another SER stated they are able to comply with OSHA standards because their mixing strategy is underground. They have storage and blending tanks outside and underground. They transfer the chlorinated solvents from one tank to another, then turn the tank over until it is mixed.

Regulatory Flexibility Alternatives

SERs identified several potential flexibility alternatives, challenges for small businesses, and questions for EPA regarding the regulatory approach.

EPA's SBAR Panel Outreach Meeting with Small Entity Representatives on Proposed Rulemaking for Methylene Chloride under TSCA Section 6(a)

- Exposure limits:
 - Several SERs asked throughout the meeting what EPA's ECEL level would be, and how it would compare to OSHA's PEL.
 - Other SERs asked if EPA has established an ECEL on any other chemical, and whether EPA has been collaborating with entities like the American Conference of Governmental Industrial Hygienists (ACGIH), which has extensive background and experience setting exposure limits.
 - One SER stated that implementing an ECEL and achieving dramatic exposure reductions would be impractical if not impossible when dealing with furniture refinishing. They recommended requiring specific worker protocols, training, or certification programs.
- Deferral to OSHA: Several SERs asked if EPA's regulatory action could be deferred to OSHA.
- Limited Access, communication with customers, and worker training:
 - One SER described how the challenge for EPA is that products containing methylene chloride can find their way into both a commercial and consumer setting. How would EPA reasonably develop a regulation that addresses the risk of such a product?
 - Another SER, a distributor, described their preference that EPA develop a limited access system that makes it easy to ask if the customers are approved by the EPA to use the product. The SER prefers checking their certification to making sure that these companies have the correct PPE.
 - The same SER, a distributor, also stated that it has the ability to make sure that customers know the product cannot go anywhere that resembles retail or has a retail component. As part of preventing retail use, they sell this product in commercial-sized containers, such as a 15-gallon keg.
 - One SER noted that in the EU, certification and training programs allow only for professional use.
 - One SER stated that methylene chloride is an acute toxin that, when used incorrectly, can kill very rapidly, but they did not think it is difficult to educate the workforce on ways of handling it appropriately.
- Personal Protective Equipment:
 - One SER provided recommendations regarding PPE, stating that full masks with polycarbonate lenses can be easily ruined and are expensive, so they recommend a half-mask where users can add a face shield or goggles.
 - This SER was supportive of a requirement to wear PPE or for respiratory controls.
- Anticipated significant impacts:
 - One SER described how, in the absence of a suitable substitute chemical, to reduce exposures to methylene chloride they would need to do a full engineering redesign and shut down of the facility, which all have high costs and could affect the

EPA's SBAR Panel Outreach Meeting with Small Entity Representatives on Proposed Rulemaking for Methylene Chloride under TSCA Section 6(a)

- availability of the products they produce (drug products and non-drug products, affecting human and veterinary markets).
- SERs with closed loop systems indicated that regulating this particular use of methylene chloride would be a huge burden on their company, as there is no way to close off part of the closed loop system. Many SERs indicated they would like an exclusion for this use.
 - Exemptions and exclusions:
 - One SER stated that EPA should consider the national emission standards for hazardous air pollutants (NESHAP) and the MIL-SPEC programs where methylene chloride is specified or regulated for a specific end use application. The SER described how those scenarios would be good to consider for exemptions and exceptions, because the potential for exposure is so low and has already been considered with these products.